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Bulgaria

Agricultural Biotechnology Annual

Bulgaria Revises Biotech Regulations

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Report Highlights:

Consumers' attitude in Bulgaria towards biotechnology is negative as anti-biotech Non-Governmental Organizations (NGO's) expand their alliances to include specialty crop sectors, such as the bee-keeping industry. During the May 2013 Parliamentary elections, for the first time, leaders in the organic and green movement openly participated in political events as representatives of the Green Party. Shortly after the elections, the appointed Cabinet issued an explicit anti-biotech declaration. It remains to be seen how this declaration will transpose into policy given the current fragile socio-economic environment wherein the latest political crisis has captured the public's immediate attention.

Section I. Executive Summary:

Bulgaria used to be a leading country in plant biotechnology research and development in mid 1990's until early 2000's. Shortly before and after EU accession in 2007, the situation changed. The major biotechnology legislation was passed in 2010 following massive anti-biotechnology campaign, and the approved legislation is believed to be one of the most restrictive in the EU. Bulgarian voting position in Brussels vary from neutral "abstain" to "against" with a few exceptions. As of today, the country does not develop any biotech products, does not grow commercially or for research purposes biotech crops, and has imposed a safeguard clause on MON 810. Bulgaria is a net importer of protein feed, mainly genetically enhanced, for the livestock sector. Currently, EC has an infringement procedure against the country for a lack of complete harmonization with the EU regulations (Directive 2009/41) and the major biotechnology law is subject to change in the next month.

Section II. Plant Biotechnology Trade and Production:

Part A: Production and Trade

a) Product Development:

No public data is available about any biotech products development. Since the major biotechnology law has been approved in 2010, biotechnology laboratories have been under an approval/registration regime by the Ministry of Environment and some were not allowed to deal with biotech products developments before their final approval is ready.

b) Commercial Production:

There is no commercial production of biotech products.

c) Exports:

Bulgaria does not export biotech products.

d) Imports:

The livestock sector depends on imported protein feed from third countries. Given the price sensitivity of the consumer market, the livestock industry imports biotech enhanced soybean meal to reduce production costs. Poultry and pork producers are in favor of importing biotech feed and derived products for their production value. However, the general consumers' opinion towards the technology is negative with some consumer organizations and NGOs advocating for import restrictions on such feed.

Corn-derived products are not imported to Bulgaria. Bulgaria is not an importer of corn gluten feed (CGF) and Distillers Dried Grains (DDGS). The local feed industry is not too familiar with either product. In addition, the supply of locally produced corn is in abundance.

e) Food Aid Recipients Countries:

Bulgaria is not a food aid recipient country. In the 1990's, the country used to accept food aid. One food aid program imported and monetized U.S. soybean meal. It is not known if the product was GE or not.

Section III. Plant Biotechnology Policy:

Part B: Policy

a) Regulatory Framework:

(i) Responsible government ministries:

Bulgaria initiated a major reform in food safety legislation and established a single Bulgarian Food Safety Agency (BFSA) that in January 2011 became operational. The new BFSA established a Risk Assessment Center to review all studies, policies, and decisions related to biotechnology. As of December 2013, the center is operational with researchers on-staff involved in biotech-related work. In 2012 into 2013 the BFSA has been adopting European Food Safety Agency (EFSA) positions and has been recommending either a positive or a neutral position to the Ministry of Agriculture on biotech-related matters.

Local legislation did not provide any formal participation of NGOs in BFSA biotech work although the Agency policy has been to take all GE-related decisions after public debate. The Coalition "Bulgaria free of GMOs," which united green and organic NGOs, demanded active participation in BFSA work to guarantee the "civil society" voice in decisions of this institution.

(ii) Biosafety Board:

Legislation created a Bio-safety Commission within the Ministry of Environment to discuss biotech-related matters and to make recommendations to the Minister of Environment. The Commission consists of scientific and NGO organizations.

(iii) Political factors/influences:

Biotechnology Legislation:

In 2010, Bulgaria passed the Biotechnology legislation, commonly referred to as the GMO (genetically modified organism) law, that governs biotechnology and that establishes the basis for a regulatory framework which is one of the most restrictive in the European Union (EU). This Law is recognized as pushing the legal limits under European and World Trade Organization (WTO) guidelines. See BU1216 for more details.

In April 2012, the European Commission (EC) notified Bulgaria to revise its legislation on biotechnology related to transposition of Directive 2009/41 on contained use of plants and plant products derived from genetic engineering (GE) (2010/2152 C(2012) 2588 of April 26, 2012 on Infringement #2010/2152). The EC considered the transposition of this directive as incorrectly completed. The EC encouraged Bulgarian authorities to revise Art.17/1 by including activities related

to GMO without a risk for human health and environment. In this way Bulgaria could harmonize local legislation with Directive 2009/41 thus eliminate the risk of sanctions due to infringement. Under the Law, Art.23 required all GMO-related work to be executed in premises (or other words laboratories) registered with the Ministry of Environment and Water Resources even in cases when this work does not pose any health/environmental risks. In response, Bulgarian authorities suggested amendments to the Law which had been developed and announced publicly on December 3, 2013 as follows: <http://www.moew.government.bg/?show=konsultacii&kid=89> .

The same amendments to the Law also suggested changes related to full harmonization of local legislation with Directive 2004/35 which references ecological responsibility related to prevention and elimination of environmental damage. EC letters dated November 2012 and February 2013 appear to be the drivers for these changes.

Finally, Bio-safety Commission received through amendments to Art.6/2 and 6/3 the following additional members: Consumer Protection Commission, Executive Agency on Environment, Bulgarian Food Safety Agency, Executive Pharmaceutical Agency etc. The Bio-safety Commission also received authority to hire, on a case-by-case basis, up to three outside scientific experts. These outside experts would not have any voting rights.

The amendments described above are open for public comment and are likely to enter into force in early 2014.

Other biotechnology related legislation which has been passed over the past year includes: Amendments to the Feed Act (#202-01-58) November 2012 which aimed to harmonize local legislation with certain EU regulations in the area of feed safety and traceability (Regulation 619/2011; Regulation 1069/2009; Regulation 142/2011, Regulations 1830/2003 and others). The Feed Act made trade in feed containing GE even stricter then before and increased the fines against illegal trade/trade with improperly labeled feed products.

The Feed Act, published in Official Gazette #97/December 7, 2012, under Decree 415 approved by the Parliament on November 23: <http://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=70784>

Bulgaria Voting Position on Biotechnology-related issues in the EU

During 2012 into 2013 Bulgaria's political approach has been to "abstain" or vote "against" on issues such as biotechnology for various reasons including public pressure from green groups. Since the winter 2009/10 anti-biotech campaign, the country has issued no positive vote on biotechnology with the exception of low-level presence (LLP) in feed. The "abstain" positions have been because the country had no local research experiments or studies to provide sufficient evidences for or against respective cases.

In December 2013, both the Ministry of Environment and Waters and the Ministry of Agriculture and Foods publicly announced their position to vote "against" the approval of GM corn 1507, according to media. The Ministry of Agriculture had a meeting with NGOs such as IFOAM- Bulgaria, Bulgarian

Association Bioproducti (Organic products); Foundation for Environment and Agriculture; Za zemiata (For Earth) NGO, Alliance “Bulgaria free of GMOs) and select bee-keepers. Media reported that Agricultural Minister Grekov position was firm not only against corn 1507 but also against all GM protein crops, and that the Ministry of Agriculture will support production of non-GM soya in Bulgaria. Earlier this fall, Bulgaria joined Danube Soya initiative (see BU1356).

GE at Parliament Hearings:

In February 2012, the then Agriculture Minister responded to two questions posed by Members of Parliament (MPs) regarding imports of GE feed. The questions were initiated by two NGOs who suspected that not all GE feed sold in the country was properly labeled. The former Ag Minister responded that all imported GE feed was approved by EC law and that only one sample of all tested in 2011 had not been properly labeled. He noted the missing mandatory label was an administrative, not a safety violation and that the lot had been recalled from the market, properly labeled then re-sold.

Biotechnology, the Ruling Party Program and New Cabinet Agenda:

In May 2013, following Parliamentary elections, the Socialist Party and the Movement for Rights and Freedom Party formed a coalition Cabinet called an expert Cabinet.

Current Cabinet Program:

The current administration has two major priorities.

First is the explicit political declaration against biotechnology. This is expected to translate into negative national positions on voting matters in Brussels and a continuation of the current restrictive regime towards biotechnology. The Cabinet plans to strongly support the organic sector that is eligible for specific support under the Common Agriculture Policy. Second is the Cabinet’s demonstrated willingness to invoke various policies in order to protect markets to encourage more local production. Although no specific actions have been announced yet, their willingness could lead to WTO inconsistent policies and non-tariff barriers on U.S. exports.

The Cabinet program contains the following priorities, in order:

- Development of a comprehensive program for building and renovating irrigation infrastructure;
- Encouragement of further development of the agricultural sector beyond monoculture in grains/oilseeds towards more processing of farm products;
- Encouragement of local farm production through development of the food industry;
- Subsidization of sectors “Vegetables production,” “Perennial crops/Orchards” and “Dairy and Livestock “to the level applied by other EU member-states. This is based on the possibility of up to 15 percent can be used in direct payments for target support;
- Specialization in organic agriculture and organic dairy/livestock production;
- Protection of population from GE foods and crops controls on quality of imported foods and of

locally produced foods.

(iv) Differing treatments between food and feed:

Treatments of food and feed differ as per EU legislation.

(v) Pending legislation:

There is pending legislation as described above in Part B/Policy/ iii- Biotechnology legislation.

b) Approvals:

Bulgaria accepts EU approved GE products for food, feed, and industrial use. However, a safeguard clause is imposed on MON 810.

c) Field Testing:

No field testing is conducted in country. The biotechnology law does not explicitly prohibit field testing but introduced conditions which make this impossible in practice.

d) Stacked Events Approvals:

Bulgaria follows EC policy in this respect.

e) Additional Requirements:

Bulgaria's 2010 biotech law prohibits growing — for research or commerce — biotech crops in all protected areas. Protected areas cover approximately 34 percent of the country's territory. The ban also extends to the surrounding area within 30 km of the protected territory (which ultimately covers the entire country and effectively bans all biotech crop trials and production), within 10 km of beehives, and within 7 km of land where organic crops are cultivated. These conditions leave no available place in the country for any field trials.

There are also additional restrictions on sales of foods with GE ingredients (see g/Labeling)

f) Coexistence:

The biotechnology law contains coexistence requirements as stated in Attachment 2 to Art. 51/4 and Art.71/3 in a list of distance from which GE crops should be kept. Distances vary from 20 meters (soybeans, flax, and peanuts) to 6,000 meters for sunflower. The distance for corn is 800 meters.

g) Labeling:

Bulgaria has two regulations (amendments to the Food Law) imposing requirements on labeling and a ban on sales of foods containing GE products in schools, kindergartens and nurseries.

The first amendment to the Food Law was published in Official Gazette #59, dated July 31, 2010. It bans use of GE products in baby food (art 5/ 4) and sales of any food containing GM in nurseries, kindergartens and in retail outlets around them (in radius of 100 meters) - art. 5/5. The ban is valid for all GE products regardless of whether or not they are approved by EC. The same is valid for sales of food with GE ingredients. In addition, sales of any food containing GE materials should be done on explicit, clearly separated shelves or stand at the retail level (art. 19). The fines for violations were increased to unheard levels of 12,500 Euro and 25,000 Euro.

The second amendment calls for special labels on GE foods when the threshold is above 0.9 percent with a clear identification of the exact quantity and type of the GE event (art. 10/2). This marking should be not less than 25 percent of the package, in capital letters and in contrast color. Food service outlets have to declare if the products they cook contain GE products even if the final products may not contain GE products in a changed form (art.12/3-5). Imports of GE foods should be accompanied by documentation with lab analysis about the exact quantity of GE and the exact event (art.24/4).

h) Trade Barriers:

The biotechnology issue has not had an impact on production and trade in conventional hybrid corn seeds for planting. Seed companies secure non-biotechnology enhanced planting seeds for the market produced in other EU Member States, Turkey or the U.S.

i) Intellectual Property Rights (IPR):

Bulgaria follows international norms on IPR although violations occur.

j) Cartagena Protocol Ratification:

Bulgaria is a signatory to Cartagena protocol and the Parliament ratified the protocol on July 19, 2000.

k) International Treaties/Fora:

Bulgaria is a member of Danube Soya initiative since November 2013 (see BU1356).

l) Related Issues:

Bulgaria usually takes a neutral or a conservative position regarding new breeding technologies.

m) Monitoring and Testing:

In the spring of 2013, the Food Safety Agency reported that all 65 food/feed samples tested during the year for GE content were negative. Comparing this to 2011 when in one of 6 samples of feed (out of total 55 food/feed tested samples) showed biotech enhanced content exceeding 5 percent of the product. But since it was indicated on the label no violation of rules occurred. In 2010, 8 of 149 tests of local foods and 10 of 113 sampled imported foods tested positive with some biotech enhanced content. The

NGOs refuted these tests and claimed that GE products, especially non-labeled feed, were on sale but no facts were presented.

n) Low-Level Presence Policy:

Bulgaria follows EU policy on LLP.

Section IV. Plant Biotechnology Marketing Issues:

a) Market Acceptance:

Market acceptance at the end-consumer level is negative. Majority of consumers have strong anti-biotech attitude without having proper knowledge or information, often accompanied by a number of myths. Sometimes it goes beyond common sense to anecdotal extremes. At a farmer level, feed and livestock producers are well aware about the availability and prices of non-GE and GE protein feed and the world market situation. Due to high price sensitivity of local consumers, most if not all imported protein feed is GE.

b) Public/Private Opinions:

Public opinion is negative towards biotechnology, and is unduly influenced by green, organic, health and consumer organizations. Surveys show consumers against any food products containing biotech components. The media does not publish anything in support of biotechnology. Political parties do not show public support for biotechnology. Farm organizations are not united on biotech issues. For example, the powerful Grain Producers Association is against biotechnology given the lack of secure markets in the EU and the stringent non-GE event requirements of their major local corn buyer, a starch manufacturing facility. Researchers are few, underfunded, and are not united in their position.

c) Market Studies:

There are no market studies about GE products.

Section V. Plant Biotechnology Capacity Building and Outreach:

Part D: Capacity Building and Outreach

a) Activities:

Post activities over the year focused on outreach developments relative to plant biotechnology. These included meetings, visits, and seminars for U.S. and EU visitors (industry research, and farm

organizations representatives), aiming to facilitate bilateral information flow, and understanding.

b) Strategies and Needs:

The following strategy for plant biotechnology capacity building and outreach is being applied:

- Provide unbiased, scientific information regarding imported animal feed and EU and world market of feed grains and protein feed including the latest product innovations, trends and their economic impact.
- Promote rational policies towards biotechnology including that for adventitious presence of non-approved biotech events and that for acceptability of products from animals fed with biotech-enhanced feed.

Section VI. Animal Biotechnology:

Part E: Production and Trade

a) Product Development:

Bulgaria has not pursued genetic engineering involving farm livestock.

b) Commercial Production:

Not applicable.

c) Exports:

Not applicable.

d) Imports:

Bulgaria does not have a system to monitor the imports of GE animals and cloned offspring or genetics from clones. Not applicable.

Part F: Policy

a) Regulation:

The Ministries of Agriculture and Health are the governing entities charged with regulating such technology.

b) Labeling and Traceability

Currently there are no labeling and traceability requirements for GE animals or cloned products

c) Trade Barriers:

There are no known trade barriers

d) Intellectual Property Rights (IPR):

There is no public information on IPR on these technologies.

e) International Treaties/Fora:

Bulgaria is not known to be a member of any international group that supports or opposes GE animals or cloning.

Part G: Marketing

a) Market Acceptance:

To date there are no studies done on this topic. However, based on conservative and negative attitude towards biotechnology, it is assumed that consumer reaction can be expected to be negative.

b) Public/Private Opinions:

Same as above.

c) Market Studies:

Same as above.

Part H: Capacity Building and Outreach

a) Activities:

In February 2012 one Bulgarian Food Safety Agency Risk Assessment Center expert participated in the State Department's Volvos training program on this topic along with representatives from other EU member states.

b) Strategies and Needs

The following strategy for animal biotechnology capacity building and outreach is being applied:

- Provide unbiased, scientific information regarding new animal biotech products on the world market and on the EU market including the latest product innovations, trends and their economic impact.

- Promote rational policies towards animal biotechnology through trainings and educational outreach in the country at the industry and regulatory level

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